



11 March 2010

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USA

**Re: NTP Listing Process for Cobalt-Tungsten Carbide Powders and Hard Metals**

Dear Dr. Lunn,

Kennametal, Inc. is submitting this letter to the U.S National Toxicology Program (NTP) for the NTP and other agencies' consideration during the review of the Background Document for the Listing Status for Cobalt-Tungsten Carbide Powders and Hard Metals in the 12th Report on Carcinogens. In summary the scientific evidence does not support the listing decision as described in the background document.

Moreover, Kennametal is concerned that inconsistent criteria are being applied across the substances being considered for the 12th Report on Carcinogens. Therefore, Kennametal urges that any listing decision be deferred until these inconsistencies have been addressed and the NTP considers forthcoming informative scientific data. Kennametal is a member of the International Tungsten Industries Association which previously submitted extensive comments expressing concerns with the scientific support for the Background Document as well as the Expert Review Panel's recommendation to List Cobalt-Tungsten Carbide Powders and Hard Metals as "reasonably anticipated to be a human carcinogen."

Kennametal has highlighted the key arguments below to ensure the NTP process gives close additional consideration to our argument that hardmetal should not be listed based upon the scientific evidence currently available.

***I. The Background Document Does Not Present Sufficient Scientific Evidence to Support a Listing Decision for Sintered Hardmetals.***

- In the occupational settings, workers are exposed to two basic forms of hardmetal: sintered versus unsintered materials. Tungsten carbide, in a

powdered form, and the binding agent, cobalt, are blended together with a variety of other metals to produce a uniform and homogeneous product. After the material is compacted and formed, it must be sintered. This process is done in a hydrogen atmosphere or vacuum furnace with temperatures ranging from 2500° F to 2900° F. This reaction results in compaction and an increase in density of hardened materials to its desired specifications.

- This distinction is critical since the vast majority of employees in the hardmetal industry, and all of the downstream users of products containing cobalt-tungsten carbide, are exposed only to sintered products. Sintered materials form hardmetal tools, drills, and bits essential to numerous industries. Exposure to unsintered materials is limited to a small percentage of those individuals involved in hardmetal production.
- The Expert Panel acknowledged the potential importance of sintering by noting that the epidemiological data and IARC suggested a decreased risk associated with exposure to sintered materials. In fact, IARC concluded that no increased risk of lung cancer was identified from exposure to sintered hardmetal (IARC 2006, p.130; NTP 2008, p.56). However, the Expert Panel did not retain this distinction in its listing recommendation.
- Further, given that all of the *in vivo* and *in vitro* toxicity testing cited in the Background Document was conducted on unsintered materials, there is insufficient animal data on sintered materials to meet the NTP's criteria for listing.
- Evaluating a material based on significant physical/chemical differences and different toxicological evidence is consistent with previous NTP assessments. For example, the Expert Panel's recommendation on listing glass wool fiber highlighted the differences in the physical properties. The panel determined that only "special fibers of concern (longer, thinner, less soluble fibers)" should be classified as a potential carcinogen.
- The NTP should ensure that its panel apply the same criteria for characterizing the physical forms of a material and evaluating the toxicological evidence for each principal form.

**II. The NTP and Expert Review Panel Failed to Consider its Own Important Study on Cobalt-Tungsten Carbide Powders.**

- Although there are no *in vivo* carcinogenicity animal studies for cobalt-tungsten carbide powders or hardmetals, an NTP-funded sub-chronic (13-week) bioassay of cobalt-tungsten carbide (*A Study of Fischer-344 Rats and B6C3F1 Mice Exposed to Cobalt and/or Tungsten Carbide Dusts for Three Months*, Brookhaven National Laboratory, 1986) reported only "minimal lung lesions" and that "neither [tungsten carbide], Co (metal), nor the combination of the two is markedly toxic at the concentrations studied." It is important to note that the form of the materials used in this study more closely resemble the

exposures to a minor portion of individuals in the workplace (i.e., unsintered powders) and not the products produced and available to downstream users (i.e., sintered).

- Portions of this study related to the methodology for exposure to combined tungsten carbide and cobalt using a fluidized bed method (Shiotsuka RN, Kutzman RS, Firriolo JM, Drew RT. 1992. Use of fluidizing bed aerosol generators to establish a dust mixture of two substances at a fixed ratio for inhalation toxicity studies. Am Ind Hyg Assoc J. 53(8):510-3.) However, the toxicological results were not published.
- Although NTP funded this study, it was not cited in the Final Background Document regarding hardmetal for the 12<sup>th</sup> Report on Carcinogens.

### **III. The Expert Review Panel Recommendation for Listing Rests on Weak Epidemiological Data.**

- The Expert Panel's recommendation for listing was based in part on "limited evidence in humans" provided in only four epidemiological studies of hardmetal workers. As noted in the Draft Background Document (December 2008), "...if we're looking for completely independent observations, one should either contemplate these two papers and dismiss the paper by Moulin *et al.* (1998) or, alternatively, dismiss them and consider only the paper by Moulin *et al.* (1998)."
- In addition to the limited number of investigations, those published reports suffered from several weaknesses that limited their ability to establish a causal relationship, including:
  - Weak reported association and effect size (SMRs of 1.3 in multi-plant studies);
  - Lack of clear exposure-response relationship;
  - Confounding (e.g., smoking and co-exposure to IARC carcinogens) not adequately addressed;
  - Unusually high percentage of "loss to follow-up;"
  - Small cohort size and low statistical power; and,
  - Lack of internal and regional external mortality comparisons.
- As with material characterization, there are inconsistent conclusions drawn by different Expert Panels when provided with similar epidemiological evidence. For example, in the glass wool fiber panel review, epidemiology evidence with comparable weak reported association and effect size (SMR 1.12-1.28) are deemed supportive of a decision not to list the material as a carcinogen. The Expert Review panel also pointed out that the excess lung cancers could easily

be explained by confounding, the same concern with the studies of hard metal workers.

- We concur that weak evidence without adequate control for known confounders does not support listing. If the NTP applied the evaluative criteria used by the Expert Panel on Glass Wool Fibers to the hard metal epidemiology studies, the analysis would not support a listing determination.

***IV. In-Progress Research on Cobalt-Tungsten Carbide and Related Constituents will Address Several Data Gaps and Allow NTP to Make a Better-Informed Recommendation.***

- The Expert Review Panel acknowledged significant data gaps associated with the assessment of the carcinogenic potential of cobalt-tungsten carbide hard metals and powders. The Background Document noted the unavailability of a single long-term (2-year) cancer bioassay on cobalt-tungsten carbide powders (sintered or unsintered) in even a single rodent species. This important data need is typically required by NTP for listing in the Report on Carcinogens.
- Ongoing research will address many of the data gaps and they could influence the Listing Recommendation for Cobalt-Tungsten Carbide Powders and Hard Metals. The research efforts include:
  - University of Pittsburgh Epidemiological Study of Hard metal Workers;
  - The NTP sub-chronic and chronic bioassays for tungsten; and,
  - The NTP two-year chronic toxicity assessment of cobalt metal powder.

In conclusion, Kennametal does not believe that the NTP has sufficient scientific data in which to continue forward with the Report on Carcinogens Listing Process for Cobalt-Tungsten Carbide Powders and Hard Metals.

Sincerely,

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Phil Wehl

Vice President, Integrated Supply Chain and Logistics

Cc: